Docket No. 2003N-0496

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE FOOD AND DRUG ADMINISTRATION'S REQUEST FOR COMMENT ON

REGULATION of QUALIFIED HEALTH CLAIMS in the LABELING of CONVENTIONAL HUMAN FOODS and DIETARY SUPPLEMENTS

February 25, 2004

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry, comprised of companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods and dietary supplements.

Background

In a Federal Register notice of November 25, 2003 the Food and Drug Administration (FDA) issued an advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. The agency also solicited comments on various other issues and on the appropriateness and nature of dietary guidance statements for foods and dietary supplements.

The agency provided a background that placed the ANPRM in the context of regulations implementing the Nutrition Labeling and Education Act of 1990 (NLEA) and judicial actions and decisions related to NLEA. The agency stated that qualified health claims are those that do not meet the current significant scientific agreement standard and discussed and identified other relevant standards, and specifically a "weight of the evidence" standard and a "credible evidence" standard. FDA identified three specific alternatives that it is considering for regulating qualified health claims and requested comments on these alternatives or options.

AHPA is submitting these comments to respond to FDA's request for comments on the options that FDA is considering for regulating qualified health claims for foods and dietary supplements. AHPA is also commenting on some, but not all, of the other issues on which FDA solicited comments.

A variation on 'Option 1' would provide the greatest benefit to consumers

FDA identified three options in the ANPRM for regulating health claims. 'Option 1' is an evidence-based ranking system that would require premarket

petition of qualified health claims and that would codify standardized qualifying language for these claims that would be dependent upon the level of scientific evidence that supports the claim. 'Option 2' would require every proposed qualified health claim to undergo notice-and-comment rulemaking. 'Option 3' would regulate qualified health claims only on a post-market basis and would apparently not require submission to FDA of any communication in advance of making a qualified health claim.

AHPA believes that, of the three alternatives identified in the ANPRM, the approach outlined in 'Option 1' provides the greatest benefit to consumers. This belief is grounded in the conviction that this regulatory model would provide the proper balance between a marketer's obligations to ensure that any qualified health claim is truthful and not misleading and the role that FDA must play in administering rules that implement the court decisions that serve as the background for this rulemaking. AHPA also believes that a system in which FDA has a responsibility to review a health claim for a food or dietary supplement, whether or not the claim is qualified, will have greater credibility for consumers.

AHPA suggests, however, that the agency reconsider its stated intention to express its decisions on petitions for qualified health claims in the form of enforcement discretion letters. Such a passive expression may be misconstrued as implying that the agency does not intend to enforce against the claim even though it could, an implication that may cause a consumer to believe that the claim is not legal. Such a misunderstanding would be to the detriment of consumers and would undermine the intention of this 'Option 1' to balance the level of evidence for a claim with appropriate qualifying language. Rather, FDA should consider a more affirmative determination that a qualified health claim is, for example, "allowed" by the agency or "is not opposed" by the agency.

AHPA further suggests that appropriate qualifying language not be limited to the language provided in Table 1 of FDA's Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements. AHPA notes that a footnote in that table states that the agency may,

during the interim period which began with the publication of this document and that will presumably continue until a final rule on this matter is established, consider other language as appropriate depending on the specific circumstances in each case. AHPA encourages the agency to adopt this same tolerance for evaluating the appropriate qualifying language on a case-by-case basis when a final rule is adopted.

On the other hand, AHPA does not believe that either 'Option 2' or 'Option 3,' as identified in the ANPRM, would be an acceptable regulation for qualified health claims. Because the courts have found that use of a properly qualified health claim is a constitutional right, FDA must not restrict that right. AHPA is aware of comments submitted on July 1, 2003 by Durk Pearson *et al.* addressed to Docket No. 02D-0515, and joins those comments in their expression that the agency "...lacks constitutional power to open a comment period..." for the purpose of regulating qualified health claims and that "once FDA determines that a claim is permissible as a qualified claim, it...lacks legal power to delay its entry into the market...to conduct a formal notice and comment rulemaking." In summary, AHPA is relying on the arguments made in this July 1, 2003 communication to opine that 'Option 2" is not a legal option.

While 'Option 3' might represent a legal approach to regulating qualified health claims the approach suggested in this alternative is flawed. To begin with, a post-market regulation of all claims for foods and dietary supplements (and in fact most consumer goods) is already undertaken by the Federal Trade Commission. AHPA can conceive of no rational argument to create a regulatory process that would be fully redundant to an existing regulatory process, albeit by another federal regulator. More importantly, AHPA believes that consumers may give less credibility to product claims which FDA has not reviewed. AHPA also wishes to point out that current regulations require marketers of dietary supplements who make statements of nutritional support and 'structure-function' claims for their products to notify FDA of these claims within 30 days of marketing. As is discussed in the ANPRM, a petition to FDA is required prior to making any health claim for a food or dietary

supplement. Thus, AHPA is not aware of any allowable claim for a food or dietary supplement, with the exception of nutrient content claims that meet established regulatory guidelines, for which there is no requirement to inform FDA.

Finally, AHPA is aware of the letter submitted by the Grocery Manufacturers of America (GMA) and others on May 14, 2003, also addressed to Docket No. 02D-0515, to propose a specific premarket notification regulation for qualified health claims. While AHPA has not yet reviewed all of the details of the GMA proposal, AHPA encourages FDA to consider publication of this proposal or a significantly similar proposal as the proposed rule for regulating qualified health claims for human foods and dietary supplements.

FDA should revise claim language for unqualified health claims.

The agency noted that the report of the Task Force on Consumer Health Information for Better Nutrition suggested that FDA consider removing the requirement in current regulations for the word "may" from unqualified health claims, and stated that the Task Force's rationale was that this would eliminate uncertainty about the science underlying claims that meet the significant scientific agreement standard.

AHPA agrees with this recommendation of the Task Force. The agency stated that it intended the requirement to use the word "may" in unqualified claims to make the point that there is no guarantee that any one dietary practice will reduce the risk of a specific disease in any one specific individual. AHPA believes, however, that individual consumers recognize that, for example, while use of a seatbelt reduces risk of head injuries there is no guarantee that any one individual will not suffer a head injury while wearing a seatbelt. Whether this message is communicated as "may reduce risk" or "reduces risk" is unlikely to modify this perception. Similarly, whether the consumer is informed that "Healthful diets with adequate folate **may reduce** a woman's risk of having a child with a brain or spinal cord defect," or alternately, "Healthful diets with adequate folate **reduces** a woman's risk of having a child with a brain or spinal cord defect," it is unlikely that

consumers believe that there will never be a child with a brain or spinal cord defect born to a woman who obtains adequate folate.

Interim Final Rules should continue to be used by FDA

FDA noted in the ANPRM that it has in three instances authorized an unqualified health claim through the interim final rule (IFR) process under section 403(r)(7) of the Federal Food, Drug, and Cosmetic Act, and the agency requested comments as to whether it should continue to utilize the IFR process.

Because AHPA believes that there is a value in providing more rather than less information to consumers and because for some consumers timeliness in the receipt of information can have significant health consequences, AHPA strongly recommends that FDA continue its established practice of using the IFR process. The agency stated that in each instance in which it has used of this process to date, the IFR was "based on a finding of [significant scientific agreement]," apparently in advance of publishing the IFR. Also, FDA noted that in the two cases in which it has issued an IFR and subsequently published a final rule, there was no difference between the interim final rule and the final rule. Thus it appears that the mechanisms that are now in place are sufficiently robust to have ensured the validity of the scientific basis for these health claims at the same time that consumers have had access to these important health messages in a timelier manner than would have been the case if the IFR process had not been used.

Acceptance of claims evaluations by outside experts

FDA asked in the ANPRM whether it should give weight to evaluations by outside scientific groups in evaluating health claims. It is common for petitioners in GRAS notifications and new dietary ingredient notifications, as well as in food additive petitions and GRAS petitions, to utilize panels of experts to review the scientific data and information available to support such notifications and petitions. It is AHPA's position that FDA should encourage the use of experts qualified by training and experience in petitions for health claims, including both qualified and

unqualified claims. Reviews by such experts should expedite FDA's own independent review of the data and information provided to support such claims.

Additional flexibility is needed for herbal dietary supplements

The ANPRM noted that the Task Force identified above suggested that FDA solicit comments on whether there needs to be additional flexibility in the current requirements that govern disqualifying nutrient levels and minimum nutrient content requirements. The ANPRM also noted that it was not requesting comments on these issues at this time as FDA intends to reopen the comment period on an earlier rulemaking where these issues were previously raised.

AHPA respects the notification that, to avoid duplication and confusion, comments on these issues be delayed. At the appropriate time AHPA will provide comments to point out that, because herbal dietary supplements are by their very nature absent the minimum nutrient requirements that are established in the current regulation, additional flexibility is needed to prevent the continuation of the *de facto* exclusion of this entire class of goods from making health claims.

Summary

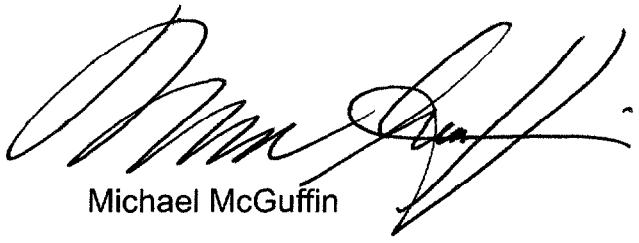
AHPA supports the development of a regulatory approach that will fully implement recent judicial decisions as to the constitutional right to make truthful and not misleading health related statements and that will encourage the development of qualified health claims. Any such regulation should be designed to maximize the amount and quality of truthful and not misleading health related information that consumers receive about foods and dietary supplements while minimizing consumer confusion.

AHPA believes that, of the three regulatory alternatives proposed by FDA in the ANPRM that is the subject of these comments, 'Option 1' provides the most effective regulation. AHPA also believes that this 'Option 1' must be modified so that regulatory outcomes affirmatively state that the agency "approves" or "is not opposed to" qualified health claims that are supported by credible evidence, and

that flexibility must be provided with regard to specific qualifying language. In addition, AHPA encourages FDA to give serious consideration to the premarket notification regulation for qualified health claims that was proposed by GMA in their communication last May, or to revisions to that proposal that may be forthcoming.

AHPA appreciates the opportunity to provide these comments and looks forward to evaluating any subsequent proposed rule in this matter.

Respectfully submitted,



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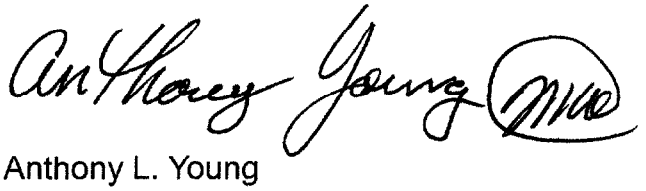

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